Arnold B. Calmann (abc@saiber.com) Jeffrey Soos (js@saiber.com) Katherine A. Escanlar (kae@saiber.com) SAIBER LLC One Gateway Center, 10th Floor Newark, New Jersey 07102 Telephone: (973) 622-3333 Facsimile: (973) 286-2465 Of Counsel: John Josef Molenda (jmolenda@steptoe.com) David L. Hecht (dhecht@steptoe.com) STEPTOE & JOHNSON LLP 1114 Avenue of the Americas New York, New York 10036 Telephone: (212) 506-3900 Facsimile: (212) 506-3950 John C. Caracappa (jcaracappa@steptoe.com) Scott M. Richey (srichey@steptoe.com) STEPTOE & JOHNSON LLP 1330 Connecticut Avenue, NW Washington, D.C. 20036 Telephone: (202) 429-3000 Facsimile: (202) 429-3902 Attorneys for Plaintiff Medidata Solutions, Inc. IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY MEDIDATA SOLUTIONS, INC., Plaintiff, Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

JURY TRIAL DEMANDED

DOCUMENT ELECTRONICALLY FILED

V.

DATATRAK INTERNATIONAL, INC.,

Defendant.

Plaintiff Medidata Solutions, Inc. (Medidata), by and through its undersigned counsel, hereby files this Complaint against DATATRAK International, Inc. (DATATRAK) and avers as follows:

PARTIES

- 1. Medidata is a Delaware corporation having its corporate headquarters and a place of business at 350 Hudson Street, Floor 9, New York, New York 10014. Medidata also maintains a place of business at 379 Thornall Street, 15th Floor, Edison, New Jersey 08837. Medidata is a leading global provider of cloud-based clinical development solutions to a diverse life science customer base that includes biopharmaceutical companies, medical device and diagnostic companies, academic and government institutions, and contract research organizations. That customer base includes more than 20 of the top 25 global pharmaceutical companies as well as organizations of all sizes developing life-enhancing medical treatments and diagnostics.
- 2. Medidata is the owner of all right, title and interest to U.S. Patent No. 8,620,677 (the '677 patent) and U.S. Patent No. 8,738,397 (the '397 patent).
- 3. On information and belief, DATATRAK is an Ohio corporation, having a place of business at 6150 Parkland Boulevard, Mayfield Heights, Ohio 44124 and operations throughout the United States, including New Jersey. On information and belief, DATATRAK is a provider of information technology to the clinical trial industry.

JURISDICTION AND VENUE

4. This action arises under the Patent Laws of the United States, Title 35 of the United States Code.

- 5. This court has subject matter jurisdiction over the causes of action asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- This Court has personal jurisdiction over DATATRAK in that DATATRAK's 6. substantial, continuous, and systematic contacts with the state of New Jersey render DATATRAK essentially at home in the state of New Jersey. On information and belief, DATATRAK conducts business, including selling services and products, within the state of New Jersey and this judicial district and directly or through intermediaries, distributes, offers for sale, sells, markets, promotes and/or advertises its products and services in the state of New Jersey and this judicial district. Furthermore, on information and belief, DATATRAK intentionally markets and provides its products, and intends to market the infringing products at issue in this action, to residents of this State and enjoys income from sales of its products in this State. Furthermore, on information and belief, DATATRAK's products and services regularly enter the stream of commerce in the state of New Jersey and this judicial district. As a result, DATATRAK purposefully avails itself of the privilege of doing business in the District of New Jersey. Moreover, by doing business in the District of New Jersey, DATATRAK avails itself of the protections of the District of New Jersey, and in turn, consents to jurisdiction in the District of New Jersey.
- 7. Venue is proper in this District, *inter alia*, pursuant to 28 U.S.C. §§ 1391 and 1400.

INFRINGEMENT OF U.S. PATENT NOS. 8,620,677 AND 8,738,397

8. On December 31, 2013, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent No. 8,620,677 entitled "Online,

interactive evaluation of research performance" (the "'677 patent") to Tracy Harmon Blumenfeld. A true and correct copy of the '677 patent is attached as Exhibit A.

- 9. Medidata owns all substantial rights in the '677 patent, including the right to exclude others from making, using, importing, offering for sale, or selling products covered by one or more claims of the '677 patent, the right to bring actions for infringement of the '677 patent, and the right to demand damages as well as injunctive relief.
- 10. On May 27, 2014, the USPTO duly and legally issued United States Patent No. 8,738,397 entitled "Distributed randomization and supply management in clinical trials" (the "'397 patent") to Benjamin Young, Glen de Vries, David Fenster, and Jonathan Lebowitsch. A true and correct copy of the '397 patent is attached as Exhibit B.
- 11. Medidata owns all substantial rights in the '397 patent, including the right to exclude others from making, using, importing, offering for sale, or selling products covered by one or more claims of the '397 patent, the right to bring actions for infringement of the '397 patent, and the right to demand damages as well as injunctive relief.

COUNT I: INFRINGEMENT OF THE '677 PATENT

- 12. Medidata hereby repeats, re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 11 above as though fully stated herein.
- 13. On information and belief, DATATRAK has infringed and continues to infringe the '677 patent in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents, by, without limitation: making, using, offering to sell, and/or selling in the United States clinical research products that are covered by one or more claims of the '677 patent. On information and belief, such products include, for example and without limitation: the DATATRAK ONE® Unified Experience.

14. DATATRAK has had actual knowledge of the '677 patent since no later than the date of the filing of this Complaint.

COUNT II: INFRINGEMENT OF THE '397 PATENT

- 15. Medidata hereby repeats, re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 14 above as though fully stated herein.
- 16. On information and belief, DATATRAK has infringed and continues to infringe the '397 patent in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents, by, without limitation: making, using, offering to sell, and/or selling in the United States clinical research products that are covered by one or more claims of the '397 patent. On information and belief, such products include, for example and without limitation: the DATATRAK ONE® Unified Experience.
- 17. DATATRAK has had actual knowledge of the '397 patent since no later than the date of the filing of this Complaint.

PRAYER FOR RELIEF

WHEREFORE, Medidata respectfully requests the following relief:

- A. Judgment in favor of Medidata, and against DATATRAK, that DATATRAK has and continues to directly infringe one or more claims of the '677 patent;
- B. Judgment in favor of Medidata, and against DATATRAK, that DATATRAK has and continues to directly infringe one or more claims of the '397 patent;
- C. Judgment awarding Medidata damages adequate to compensate for
 DATATRAK's infringement in an amount to be proven at trial, together

with pre-judgment and post-judgment interest and costs, as fixed by the Court;

- D. Judgment declaring that this is an exceptional case and awarding Medidata its reasonable costs and attorney fees in this matter, pursuant to 35 U.S.C. § 285;
- E. Judgment in favor of Medidata, and against DATATRAK, that interest, costs, and expenses be awarded in favor of Medidata; and
- F. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. Rule 38(b), Medidata demands a trial by jury of all issues triable as of right to a jury.

Dated: March 26, 2015

SAIBER LLC

Attorneys for Plaintiff Medidata Solutions, Inc.

s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
One Gateway Center, 10th Floor
Newark, New Jersey 07102
Telephone: (973) 622-3333

Facsimile: (973) 286-2465

Of Counsel:

John Josef Molenda (jmolenda@steptoe.com) David L. Hecht (dhecht@steptoe.com) STEPTOE & JOHNSON LLP 1114 Avenue of the Americas New York, New York 10036

Telephone: (212) 506-3900

Facsimile: (212) 506-3950

John C. Caracappa (jcaracappa@steptoe.com) Scott M. Richey (srichey@steptoe.com) STEPTOE & JOHNSON LLP 1330 Connecticut Avenue, NW Washington, D.C. 20036 Telephone: (202) 429-3000

Facsimile: (202) 429-3902

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiff Medidata Solutions, Inc., by its undersigned counsel, hereby certifies pursuant to Local Civil Rule 11.2 that the matter in controversy in this case is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceedings.

Dated: March 26, 2015

SAIBER LLC

Attorneys for Plaintiff Medidata Solutions, Inc.

s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
One Gateway Center, 10th Floor
Newark, New Jersey 07102
Telephone: (973) 622-3333

Telephone: (9/3) 622-3333 Facsimile: (9/3) 286-2465

Of Counsel:

John Josef Molenda

(jmolenda@steptoe.com)
David L. Hecht
(dhecht@steptoe.com)
STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, New York 10036
Telephone: (212) 506-3900
Facsimile: (212) 506-3950

John C. Caracappa (jcaracappa@steptoe.com) Scott M. Richey (srichey@steptoe.com) STEPTOE & JOHNSON LLP 1330 Connecticut Avenue, NW Washington, D.C. 20036 Telephone: (202) 429-3000

Telephone: (202) 429-3000 Facsimile: (202) 429-3902

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Under Local Civil Rule 201.1, Plaintiff Medidata Solutions, Inc., by its undersigned counsel, hereby certifies that Medidata Solutions, Inc. seeks damages, excluding interest, costs and punitive damages, in excess \$150,000. This action is, therefore, not appropriate for compulsory arbitration.

Dated: March 26, 2015

SAIBER LLC

Attorneys for Plaintiff Medidata Solutions, Inc.

s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
One Gateway Center, 10th Floor
Newark, New Jersey 07102
Telephone: (973) 622-3333

Telephone: (973) 622-3333 Facsimile: (973) 286-2465

Of Counsel:

John Josef Molenda (jmolenda@steptoe.com) David L. Hecht (dhecht@steptoe.com) STEPTOE & JOHNSON LLP 1114 Avenue of the Americas New York, New York 10036

Telephone: (212) 506-3900 Facsimile: (212) 506-3950

John C. Caracappa (jcaracappa@steptoe.com) Scott M. Richey (srichey@steptoe.com) STEPTOE & JOHNSON LLP 1330 Connecticut Avenue, NW Washington, D.C. 20036 Telephone: (202) 429-3000

Facsimile: (202) 429-3902